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DESCRIPTION

INFUSION CONTAINER AND METHOD FOR STORING FREEZE-DRIED MEDICINE THEREIN

Technical Field

The present invention relates to an infusion container and a method for storing a freeze-dried medicine therein. More particularly, it relates to an infusion container for preserving a freeze-dried medicine and its dissolving liquid in a separate state, and for mixing the freeze-dried medicine and the dissolving liquid in the container in a sterile manner just before the use to supply the mixture as a solution for infusion, and a method for storing a freeze-dried medicine in the infusion container.

Background Art

For storing a freeze-dried medicine in an infusion container of this kind, a large amount of a medicine is freeze-dried in advance and divided into predetermined amounts (amounts equivalent to one-container units) and the predetermined amount of medicine is charged into a medicine storing chamber of the infusion container, or alternatively, as described in, for example, Japanese Patent Nos. 2551881 and 2767016, a medicine is freeze-dried in advance using specific

small containers and the freeze-dried medicine of a predetermined amount is taken out from the small container and charged into the medicine storing chamber of the infusion container.

However, it takes a lot of trouble to perform a series of steps of crushing the freeze-dried medicine, measuring out the crushed freeze-dried medicine by a predetermined amount, and filling the infusion container with it. In the case where the small containers are used, it takes trouble especially to take the freeze-dried medicine out from the small container and there may possibly be a loss produced by an expensive freeze-dried medicine remaining in the small container.

Thus, it is a main purpose of the present invention to provide an infusion container in which a freeze-dried medicine can conveniently be stored in a medicine storing chamber thereof.

It is another main purpose of the present invention to provide an infusion container in which a medicine freeze-dried in a small container for freeze-drying a medicine is capable of being stored in a medicine storing chamber with no loss produced by a remaining medicine.

Disclosure of Invention

The present invention provides an infusion container comprising a medicine storing chamber for storing a medicine

and a dissolving liquid storing chamber for storing a dissolving liquid, the dissolving liquid storing chamber being connected with the medicine storing chamber, characterized in that the medicine storing chamber holds a small container having an open mouth and storing a freeze-dried medicine, and is so constructed as to be partitioned from the dissolving liquid storing chamber when the infusion container is out of use and preserved and to be capable of being communicated with the dissolving liquid storing chamber when in use.

Namely, in the present invention, since a small container for storing a freeze-dried medicine having an open mouth is held in a medicine storing chamber, a medicine freeze-dried in advance in the small container can be stored in the medicine storing chamber along with the small container, so that there is no need for taking the medicine out from the small container, thereby making a medicine storing process very simple and thus eliminating a loss produced by a remaining medicine.

Here, the small container needs to be a container (having, for example, an area in the mouth of 2-3 cm^2 and a height of 1.0-1.5 cm) in which a medicine is capable of being stored in a state where it is dissolved (in a state before it is freeze-dried) on the order of 0.5-4.0 ml and an open mouth is provided for allowing freeze-drying of the medicine and passage of the dissolving liquid and which is capable of being held in

the medicine storing chamber of the infusion container. Further, it is preferable that the small container can be positioned in the medicine storing chamber of the infusion container. An example of a means for positioning the small container in the medicine storing chamber is a fitting portion provided in the medicine storing chamber for fitting a part of the small container. A specific example of the fitting portion is a protruding piece. Specific example(s) of the protruding piece is/are protrusion(s) and/or a ridge formed on a container body of the medicine storing chamber to fit, respectively, longitudinal groove(s) formed in side walls and/or a trench formed in a bottom wall of the small container.

Also, the small container, which has the open mouth as mentioned above, may have, on the open mouth, a lid with an opening formed for passage of the dissolving liquid.

Further, the small container is made of synthetic resin such as polyethylene, polypropylene, polyvinyl chloride or cyclic polyolefin, or metal such as aluminum or stainless steel, and preferably of polyethylene, polypropylene or cyclic polyolefin.

Specific examples of the active ingredients in a freeze-dried medicine stored in the medicine storing chamber of the infusion container according to the present invention along with the small container are as follows.

Antibiotics are, for example, cephem antibiotics such

as cefazolin sodium, ceftizoxime sodium, cefotiam hydrochloride, cefmenoxime hydrochloride, cephacetrile sodium, cefamandole sodium, cefaloridine, cefotaxime sodium, cefotetan sodium, cefoperazone so dium, cefsulodin sodium, ceftezole sodium, cefpiramide sodium, cefmetazole sodium, cefuroxime sodium and cefocules sulfate, and penicillin antibiotics such as ampicillin sodium, carbenicillin disodium, sulbenicillin disodium, and ticarcillin sodium and, further, vancomycin hydrochloride. Antitumor agents are, for example, mitomycin C, fluorouracil, tegafur, and cytarabine. Antiulcer agents are, for example, famotidine, ranitidine hydrochloride, and cimetidine.

The dissolving liquid stored in the dissolving liquid storing chamber of the infusion container according to the present invention may be a physiological saline solution, a glucose solution, or an amino acid solution containing cysteine, tryptophan or the like. However, the dissolving liquid is not specifically limited thereto.

A capping member according to the present invention specifically comprises, for example, a pierceable plug body and a lid portion optionally attached to the plug body.

According to a preferable embodiment of the present invention, a chamber for storing a medicine alternation preventive agent may be formed on the capping member sealing the mouth portion of the medicine storing chamber (as a

specific embodiment, on the above-mentioned lid portion) preferably, so as to store a desiccant and/or a deoxidant inside as a medicine alternation preventive agent. The desiccant serves to stabilize medicines which deteriorate by humidity and may contain silica gel, zeolite or the like as components. The deoxidant serves to prevent alternation of medicines which are easily oxidized and may contain active iron oxide, amorphous copper or the like. The desiccant and the deoxidant may be suitably used depending on the kind or the like of the medicine to be stored in the medicine storing chamber. The desiccant and the deoxidant may be used alone or in combination.

Preferably, the dissolving liquid storing chamber according to the present invention is a flexible container molded into a bag-like shape by fusing comparatively flexible synthetic resin sheet such as polyethylene, polypropylene, or polyvinyl chloride, or blow-molded out of such synthetic resin. In an embodiment, the medicine storing chamber mentioned above may also be such a flexible container as above, so that both containers can be molded integrally (the double-bag system).

In one aspect, the present invention provides a small container for freeze-drying a medicine which has a small container-like shape and which has, in side walls and/or in a bottom wall thereof, respectively, a longitudinal groove and/or

a trench for insuring a fit in a medicine storing chamber of an infusion container and for positioning the container itself in the medicine storing chamber.

In another aspect, the present invention provides a method for storing a freeze-dried medicine in an infusion container which comprises the medicine storing chamber for storing a medicine and a dissolving liquid storing chamber for storing a dissolving liquid, the dissolving liquid storing chamber being connected with the medicine storing chamber and being so partitioned from the medicine storing chamber that an inside of the dissolving liquid storing chamber is capable of being communicated with an inside of the medicine storing chamber when in use, the method comprising the steps of, for storing the medicine in the medicine storing chamber of the infusion container, filling a small container having an open mouth with a solution prepared by dissolving the medicine, freeze-drying the solution by an ordinary method, and storing the freeze-dried medicine in the medicine storing chamber along with the small container without taking the freeze-dried medicine out from the small container.

Brief Description of Drawings

Fig. 1 is a longitudinal sectional view of an embodiment of an infusion container according to the present invention;

Fig. 2 is a longitudinal sectional view of the embodiment in which the infusion container is viewed from an angle different by 90° from that in Fig. 1;

Fig. 3 is a sectional view taken along line A-A of Fig. 2;

Fig. 4 is a partially exploded perspective view mainly illustrating an open state of communication holes;

Figs. 5(A), (B) and (C) are plan view, partially longitudinal sectional view, and bottom view, respectively, of a small container for freeze-drying a medicine;

Fig. 6 is perspective view of the small container for freeze-drying a medicine illustrated in of Figs. 5(A), (B) and (C).

Best Mode for Carrying Out the Invention

Hereafter, the present invention will be detailed on the basis of an embodiment illustrated in the drawings. This is not to restrict the present invention.

Fig. 1 is a longitudinal sectional view of an embodiment of an infusion container according to the present invention; Fig. 2 is a longitudinal sectional view of the embodiment in which the infusion container is viewed from an angle different by 90° from that in Fig. 1; Fig. 3 is a sectional view taken along line A-A of Fig. 2; Fig. 4 is a partially exploded perspective view mainly illustrating an open state of communication holes; Figs. 5(A), (B) and (C) are plan view,

partially longitudinal sectional view, and bottom view, respectively, of a small container for freeze-drying a medicine; Fig. 6 is perspective view of the small container for freeze-drying a medicine illustrated in Figs. 5(A), (B) and (C).

An infusion container 10 illustrated in Figs. 1 and 2 mainly comprises a medicine storing chamber 1 in which a freeze-dried medicine (not illustrated) is stored and a dissolving liquid storing chamber 2 in which a dissolving liquid (not illustrated) is stored.

The medicine storing chamber 1 is a container with a wide mouth. The medicine storing chamber 1 comprises a container body 8 with a bottom thereof connected with the dissolving liquid storing chamber 2; a small container 15 for freeze-drying a medicine, the small container being held in the container body; a freeze-dried medicine freeze-dried in advance and stored intact in the small container; and a capping member 3. The container body 8 has, at an upper end thereof, a mouth portion 1a to which the capping member 3 can be mounted, and has a communication hole 5 mentioned later at a bottom portion 6. The container body 8 is integrally formed as a whole of polypropylene and made more rigid than the dissolving liquid storing chamber 2.

The dissolving liquid storing chamber 2 is blow-molded out of transparent polypropylene into a liquid-impermeable, flat bag-like shape (to a thickness of 0.2-0.5 mm) and has

sufficient flexibility and resiliency. At an upper portion of the dissolving liquid storing chamber 2 is formed a flanged mouth 2b which is connected with a port 1b formed at a lower end portion of the medicine storing chamber 1. At a lower peripheral portion 2a of the dissolving liquid storing chamber 2 there is formed a suspension hole portion 23 as a suspension support portion. The medicine storing chamber 1 and the dissolving liquid storing chamber 2 are connected by, thermal welding the port 1b of the medicine storing chamber 1 and the flanged mouth portion 2b of the dissolving liquid storing chamber 2. Alternatively, the medicine storing chamber 1 and the dissolving liquid storing chamber 2 may be integrally molded.

At the bottom portion 6 of the medicine storing chamber 1 connected to the dissolving liquid storing chamber 2 in a liquid-impermeable manner, there is formed the communication hole 5 (communication holes 5a and 5b) for allowing communication between the medicine storing chamber 1 and the dissolving liquid storing chamber 2 and further there are formed a pair of protrusions 7c and 7d as a protruding piece 7 which protrudes into the medicine storing chamber 1, covers and seals the communication hole 5. The protrusions 7c and 7d are in the shape of towers arranged side by side, and have ribs 7f and 7g in the shape of fins for providing strength against a twist. The protruding piece 7 has fan-like

cut portions (or openings) 7a and 7b at a bottom portion 7e common to the protrusions 7c and 7d. Here, the fan-like communication holes 5a and 5b at the bottom portion 6 of the medicine storing chamber 1 are formed to oppose to each other relative to the center of the bottom portion 6 and each have a central angle of about 90° . The fan-like cut portions 7a and 7b are formed in correspondence to the above communication holes 5a and 5b. The cut portions 7a and 7b at the bottom portion 7e are adjusted to the pair of fan-like communication holes 5a and 5b formed at the bottom portion 6 of the medicine storing chamber 1 by the rotation of the protrusions 7c and 7d, whereby the medicine storing chamber 1 and the dissolving liquid storing chamber 2 are brought into communication. Here, reference numeral 7h represents a ridge which serves as a part of the protruding piece 7 formed on the bottom portion 7e.

Tip portions of the protrusions 7c and 7d are inserted into (engaged with) engaging holes 20d and 20e formed in a rubber plug 20, mentioned later, of the capping member 3. Y-shaped claws 31 and 32 formed on a ceiling of the capping member 3 are allowed to fit the Y-shaped cavities 21 and 22 formed in an upper surface of the rubber plug 20 so that the rotation of the capping member 3 can be conveyed to the rubber plug 20.

Accordingly, before the use, the communication holes

5a and 5b are closed by the bottom portion 7e in a liquid-impermeable manner as shown in Fig. 1, while the bottom portion 7e rotates via the engaging holes 20d and 20e and the protrusions 7c and 7d in accordance with the rotation of the capping member 3, whereby the communication holes 5a and 5b are adjusted to the cut portions 7a and 7b for allowing communication between the medicine storing chamber 1 and the dissolving liquid storing chamber 2, as shown in Fig. 4.

Ultra high molecular weight polyethylene is laminated to lower side surfaces of the rubber plug 20 (especially, of a rubber body 20a mentioned later) so as to facilitate the rotation for dissolution of the freeze-dried medicine in the dissolving liquid (so as to reduce frictional resistance to the mouth portion 1a). Also, an O-ring packing 33 is interposed among the rubber plug 20, the mouth portion 1a of the medicine storing chamber 1 and the capping member3 for improving liquid-impermeability.

In the meanwhile, the protruding piece 7 is made of a mixture of polypropylene in 10-30 % and polyethylene in 90-70 %, and the medicine storing chamber 1 is made of polypropylene in 100 %. These are bonded with resin (provisionally fixed) so as to secure the tightness of the communication holes 5a and 5b until the medicine is mixed with the dissolving liquid.

Two projections 11 and 12 are formed equiangularly on

the outer periphery of an opening of the container body 8 of the medicine storing chamber 1, while in an internal surface of the capping member 3 are formed depressions 34 and 35 for restricting the movement of the capping member 3 relative to the projections 11 and 12 in the range of 90° .

Also, a pair of steps 40 and 41 are spaced at 180° intervals on an outer periphery of the container body 8 for making it easier to hold the container body 8 during the rotation of the capping member 3 as mentioned later (see Fig. 2).

The rubber plug (plug body) 20 of the capping member 3 is inserted into the mouth portion 1a of the medicine storing chamber 1 for keeping the medicine storing chamber 1 airtight. The rubber plug 20 has a double structure of a rubber body 20a of a chlorinated butyl rubber selected for improving stability toward the medicine (in a solid form), the rubber body 20a occupying most area of the rubber plug 20, and a small rubber plug portion 20b positioned substantially at the center of the upper surface of the rubber body 20a and corresponding in shape to a cut hole 3b serving as an opening 4 for a medicine solution delivery portion 4 of the lid portion 3a of the capping member 3 for prevention of liquid leakage after insertion of puncture needle. Though the small rubber plug 20b is made of isoprene rubber with good restoration properties and partially exposed via the cut hole 3b, the cut

hole 3b is protected by an upper lid portion 9 so that the upper surface of the rubber plug 20 may not be contaminated. The upper lid portion 9 is attached to the capping member 3 by welding. The upper lid portion 9 is opened by pulling a puller piece 9a and thereby breaking the weld, so that the small rubber plug 20b appears via the cut hole 3b. The upper lid portion 9 has a flat upper surface that allows the infusion container 10 filled with a freeze-dried medicine and a dissolving liquid to stand by itself.

In a lower surface of the rubber plug 20a, there is formed a lower recess 20c for facilitating the insertion of the puncture needle and engaging holes 20d and 20e for engaging with the tip portions of the protrusions 7c and 7d. The engaging holes 20d and 20e have a diameter of 2-6 mm.

In Figs.1-6, especially in Figs. 5(A), (B) and (C) and Fig. 6, the small container 15 for freeze-drying a medicine is a substantially cylindrical container with an open mouth. The small container 15 has longitudinal grooves 36 and 37 in side walls, and a trench (transverse groove) 38 in a bottom wall in a continuous manner. The small container 15 is molded out of polypropylene to a mean material thickness of 0.5-1.0 mm.

The small container 15 stores the freeze-dried medicine intact in a state where it was freeze-dried therein, and is positioned in the medicines-storing container 1, especially as illustrated in Figs. 1-4.

Namely, before the rubber plug 20 of the capping member 3 is mounted in the mouth portion 1a, the small container 15 is allowed to enter via the mouth portion 1a and positioned by engaging the longitudinal grooves 36 and 37 and the trench 38 of the small container 15 with, respectively, the protrusions 7c and 7d and the ridge 7h serving as the protruding piece 7. The freeze-dried medicine was obtained by filling the small container with a solution prepared by dissolving the medicine and freeze-drying the solution in a separate freeze-dryer by an ordinary method.

By such a construction of the infusion container 10, when the capping member 3 is rotated, the rubber plug 20 rotates in accordance therewith and further the protrusions 7c and 7d rotate via the engaging holes 20d and 20e of the rubber plug 20 to break the resin-bonding (provisional fixing) made to the bottom portion 6 of the medicine storing chamber 1, whereby the large communication hole 5 (communication holes 5a and 5b) is easily formed between the medicine storing chamber 1 and the dissolving liquid storing chamber 2 (see especially Fig. 4).

Further, the dissolving liquid is allowed to flow into the medicine storing chamber 1 via the communication hole 5 by reversing the infusion container 10 or pressing the dissolving liquid storing chamber 2. Thus, the dissolving liquid enters the small container 15 for freeze-drying a

medicine from the mouth thereof and the freeze-dried medicine in the small container 15 is quickly dissolved therein (normally, a freeze-dried medicine is easily and instantly dissolved in a dissolving liquid).

Subsequently, a medicine solution obtained by mixing the freeze-dried medicine with the dissolving liquid is taken out as an infusion fluid at one end of a drip infusion device (not illustrated, the same with the below) by removing the upper lid portion 9 with the puller piece 9a to open the cut hole 3b serving as the medicine solution delivery portion 4, inserting into the exposed small rubber plug portion 20b of the rubber plug 20 the puncture needle integrally connected to the drip infusion device at the other end to pierce the rubber plug 20a, and hanging the suspension hole portion 23 of the dissolving liquid storing chamber 3 on a stand. Thus, in the above embodiment, the communication between the medicine storing chamber 1 and the dissolving liquid storing chamber 2 is achieved with extreme ease by the rotation of the capping member 3.

Also, the sterility inside the infusion container 10 is secured because the container is, due to the flat shape of dissolving liquid storing chamber 2 itself and its resiliency, capable of discharging the dissolving liquid by finally taking the shape of a plate even without allowing the outside air to enter (even without using an air needle) during the drip

infusion, so that the medicine solution is not in contact with the air until the drip infusion is finished. Further, since all the components of the infusion container 10 exclusive of the rubber plug are made of plastics consisting only of polyethylene and polypropylene described in (Japanese Pharmacopoeia Tests on Plastics for Containers for Solutions for Infusion), it is unnecessary to classify the components depending on whether they are made glass or metal in discarding the infusion container 10 containers as needed with conventional infusion containers (infusion kits) when the drip infusion is finished.

As mentioned above, according to this infusion container, the protruding piece seals the communication holes formed at the bottom of the medicine storing chamber and the protruding piece engaged with the rubber plug is released from the bottom of the medicine storing chamber by the rotation of the capping member via the rubber plug to open the communication holes, whereby the medicine storing chamber and the dissolving liquid storing chamber are brought into communication, making it possible to provide a solution for infusion easily and in a sterile manner.

Industrial Applicability

According to the present invention, a medicine freeze-dried in advance in the small container for freeze-drying

a medicine is capable of being held in the medicine storing chamber along with the small container, so that there is no need for taking the medicine out from the small container, thereby making a medicine storing process very simple and thus eliminating a loss produced by a medicine remaining in the small container.